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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,602	06/30/2000	Matthew Joseph Doyle	8141	8543

27746 7590 12/27/2001

THE PROCTER & GAMBLE COMPANY
PATENT DIVISION
HEALTH CARE RESEARCH CENTER
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MASON, OH 45040

EXAMINER

DECLoux, AMY M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 12/27/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/607,602

Applicant(s)

Doyle et al.

Examiner

DeCloux, Amy

Art Unit

1644

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Oct 29, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-7 is/are pending in the applica

4a) Of the above, claim(s) 1, 5, and 6 is/are withdrawn from considera

5) ☐ Claim(s) is/are allowed.

6) ☐ Claim(s) is/are rejected.

7) ☐ Claim(s) is/are objected to.

8) ☒ Claims 2-4 and 7 are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2

20) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of Group VIII (Claims 2-4 and 7) and cimetidine as the single species of H2 antagonist, in Paper No. 4, filed 10-29-01 is acknowledged. The traversal is on the ground(s) that the present composition claim and method claim are so closely related that they should be prosecuted in the same application. Upon further consideration, the examiner will limit the examination of claim 1 and its dependents to the subgenus of H-2 antagonists. In the instant case it would constitute a serious undue burden on the Examiner to search all recited species for the reasons of record and because a search in the non-patent literature of any of these distinct inventions would not be co-extensive with a search of the others. The restriction is still deemed proper and is therefore made FINAL.
2. Claims 5-6 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.
3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.
4. Claims 1-4 and 7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.
 - A) Claims 1-4 and 7 are indefinite in the recitation of "whole body health" because it is not clear exactly what said phrase encompasses.
 - B) Claim 7 is indefinite in the recitation of the phrase "dentinal desensitizing agents" because the instant disclosure does not define said phrase.
 - C) claims 3-4 and 7 are indefinite for being in improper Markush format. The Office recommends inserting ---the group consisting of----
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --
 - (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
 - (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
6. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Pan et al (WO 97/16159).

Pan et al teaches that histamine H2 receptor antagonists including cimetidine may be employed in an oral composition in an amount effective to treat or prevent inflammations in the oral cavity said composition may also comprise essential oils to act as antimicrobial agents. Therefore the referenced teachings anticipate the claimed invention. It is noted that the whole body health benefits are inherent in the referenced methods. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See MPEP 2112-2112.02. Also, see Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). Preamble language in claims of patents directed to administration of anticancer drugs are expressions of purposes and intended results, and as such are nonlimiting, since language does not result in manipulative difference in steps of claims. The instant case does not present a situation in which the new use of a process should be considered limiting because it distinguishes process over prior art (Bristol Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001), previously 00-1304 (CAFC 4/20/01).

Therefore, the referenced teachings anticipate the claimed invention.

7. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Singer et al (U.S. No. 5,364,616).

'616 teaches a method for treatment and prevention of gingivitis or periodontitis comprising the topical administration of the oral cavity of a composition comprising a histamine-2 receptor antagonist compound in the form of a dentifrice, mouthwash, mouth rinse, mouth spray, or dental treatment solution (see entire patent especially the abstract and claims 1-8 and column 21, lines 5-18). '616 also teaches that the compositions used said methods can be in the form of a toothpaste, tooth gels, tooth powders, chewing gum, which may act as odor masking agents (see entire patent especially column 15, lines 24-60, and claims 9-15). '616 also teaches that the compositions used in said methods can be a non abrasive gel as disclosed in column 16 lines 5-12, which teaches silica gels that do not abrade dentin. '616 also teaches that the compositions used in said methods can be a dental implement such as a control release delivery system as taught in column 20, lines 44-65, and can be comprised of cellulose hollow fibers (column 16, lines 46-50) which is consistent with the definition of a dental implement disclosed on page 30, lines 17-18 of the instant application. '616 also teaches that the compositions used in said methods can encompass antimicrobial/antiplaque agents which include antibiotics (column 18, lines 48-51), biofilm inhibiting agents such as surfactant (column 17, lines 46-62), and analgesics such as aspirin (column 19 lines 10-17). It is noted that the whole body health benefits are inherent in the referenced methods. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See MPEP 2112-2112.02. Also, see Ex parte Novitski 26 USPQ

1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). Preamble language in claims of patents directed to administration of anticancer drugs are expressions of purposes and intended results, and as such are nonlimiting, since language does not result in manipulative difference in steps of claims. The instant case does not present a situation in which the new use of a process should be considered limiting because it distinguishes process over prior art (Bristol Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001), previously 00-1304 (CAFC 4/20/01)).

Therefore, the referenced teachings anticipate the claimed invention.

8. Claims 1- 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsujita et al (JP 04089428A).

Tsujita et al teaches a method of treating the oral cavity disease of gingivitis comprising cimetidine as an active ingredient (see abstract only, since the rest of the patent is in Japanese). It is noted that the whole body health benefits are inherent in the referenced methods. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See MPEP 2112-2112.02. Also, see Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). Preamble language in claims of patents directed to administration of anticancer drugs are expressions of purposes and intended results, and as such are nonlimiting, since language does not result in manipulative difference in steps of claims. The instant case does not present a situation in which the new use of a process should be considered limiting because it distinguishes process over prior art (Bristol Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001), previously 00-1304 (CAFC 4/20/01)).

Therefore, the referenced teachings anticipate the claimed invention.

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the

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PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner,
Group 1640
December 21, 2001

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1647